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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,705	03/18/2004	Annemarie Wolleb	HL/95-22204/A/PCT/DIV	7819
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CIBA SPECIALTY CHEMICALS CORPORATION			GRAZIER, NYEEMAH	
PATENT DEPARTMENT			ART UNIT	
540 WHITE PLAINS RD			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,705	WOLLEB ET AL.	
	Examiner	Art Unit	
	Nyeemah Grazier	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17, 19-21, 23, 24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 15-17, 23, 24, 26 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 and 14 is/are allowed.
- 6) ☒ Claim(s) 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

I. ACTION SUMMARY

Claims 13-17, 19-21, 23, 24, 26, 27 are currently pending. Claims 15-17, 23, 24, 26, and 27 are withdrawn from further consideration by the Examiner because Claims 15-17, 23, 24, 26, and 27 are drawn to a non-elected invention. 37 C.F.R. § 1.142(b).

Claims 19-21 are rejected to as being unpatentable over Kathawala (U.S. Pat. No. 4,739,073) as applied to claim 19 above, and further in view of Jerry March, Advanced Organic Chem. 3rd Ed., 1985, pp. 809, 431 and 432.

II. PRIORITY

Priority

This application is a Divisional of U.S. Application 10/296,106, now U.S. Pat. 6,743,926, which is a 371 of PCT/EP01/05667, filed on May 17, 2001. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European Patent Office on May 26, 2000.

III. RESTRICTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 13, 14, 19-21 drawn to the compounds of formula (2) and (3), classified in class 548, subclass 491.
- II. Claim 15, drawn to the process of synthesizing the compound of formula (2), classified in class 548, subclasses 486, 490, 491.

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- III. Claims 16 and 17, drawn to a process of synthesizing the compound of formula (2), classified in class 548, subclass 491.
- IV. Claims 23, 24, 26 and 27, drawn to intermediate compounds of formulae (8) and (5), classified in class 548, subclasses 490 and 491.

Rationale

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of formulae (2) can be synthesized by reacting the compound of formula (5) with a compound that introduces the radical of formula $-\text{CH}=\text{CH}-\text{Z}$; or by reacting a compound of formula (9) with a compound of formula $\text{CH}_3\text{-CO-CH}_2\text{-COOR}_2$. (See Specification, pp. 4-5, and 8-9).

Inventions I and III are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of formulae (2) can be synthesized by reacting the compound of formula (5) with a compound that introduces the radical of formula $-\text{CH}=\text{CH}-\text{Z}$; or by reacting a compound of formula (9) with a compound of formula $\text{CH}_3\text{-CO-CH}_2\text{-COOR}_2$. (See Specification, pp. 4-5, and 8-9).

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Inventions I and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as intermediates in the preparation of compounds of formula (1), which is useful as a cholesterol-biosynthesis inhibitor and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Invention II and III are unrelated processes. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions use different synthesis and different reagents. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Additionally, the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper.

Inventions II and IV are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of formulae (8) an intermediate is not essential to the process of making formula (2) as claimed in Claim 15 because the compound of formula (2) can be made by reacting the compound of formula (5) with a compound that introduces the radical of formula $-\text{CH}=\text{CH}-\text{Z}$; or by reacting a compound of formula (9) with a compound of formula $\text{CH}_3\text{-CO-CH}_2\text{-COOR}_2$. (See Specification, pp. 4-5, and 8-9). Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Additionally, the search required for Group II is not required for Group IV, restriction for examination purposes as indicated is proper.

Inventions III and IV are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of formulae (9), an intermediate, is not essential to the process of making formula (2) as claimed in Claim 17, because the compound of formula (2) can be made by reacting the compound of formula (5) with a compound that introduces the radical of formula $-\text{CH}=\text{CH}-\text{Z}$; or by reacting a compound of formula (9) with a compound of formula $\text{CH}_3\text{-CO-CH}_2\text{-COOR}_2$. (See Specification, pp. 4-5, and 8-9). Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Additionally, the search required for Group II is not required for Group IV, restriction for examination purposes as indicated is proper.

Advisory of Rejoinder

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312.

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Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Pursuant to M.P.E.P. § 821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in

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order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

IV. ELECTION

During a telephone conversation with Kevin Mansfield, Esquire on June 29, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 13, 14, and 19-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-17 and 23, 24, 26 and 27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

V. REJECTIONS

35 USC § 103 Obviousness Rejection

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

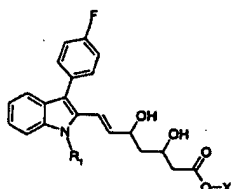
Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

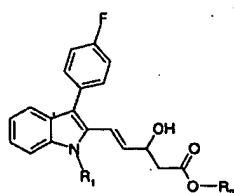
Claims 19 - 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kathawala (U.S. Pat. No. 4,739,073) as applied to claim 19 above, and further in view of Jerry March, Advanced Organic Chem. 3rd Ed., 1985, pp. 809, 431 and 432.

The instant inventions in Claims 19-21 recite indole derivatives of Formula (1) and intermediate



(1).

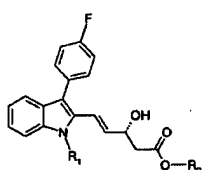
compounds thereof. Specifically, the invention is drawn to the compound of Formula (3).



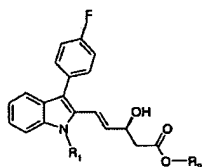
(3).

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Claim 19 broadly claims the compound of Formula (3) wherein R₁ is C1-C6alkyl and R₂ is hydrogen or a hydrocarbon radical. Dependent Claim 20 recite the compound of Formulae (3a) or (3b) wherein R₁ and R₂ are as defined in Claim 19.



(3a) or

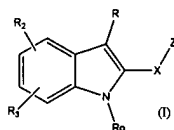


(3b)

Finally, Claim 21 depends from Claim 20, wherein R₁ is isopropyl and R₂ is C1-C6alkyl.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Kathawala (4,739,073) teaches intermediates in the synthesis of indole analogs of mevalonolactone and derivatives thereof represented by the generic formula (I):



wherein the variables of the generic molecule is identical to Formula (I) of the instant application. (U.S. 4,739,073, cols. 1-2). Specifically, R₂ and R₃ are hydrogen atoms, R is a phenyl ring substituted by fluoro, R_o is a secondary C1-C6alkyl, X is -CH=CH-, and z is -

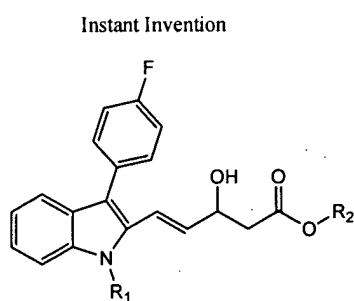
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CHOH-CH₂-CHOH-CH₂-COOR, wherein R can be alkyl or hydrogen. (U.S. 4,739,073, cols. 1-2). Thus, Kathawala teaches the identical compound of Claims 19-21 of the instant application.

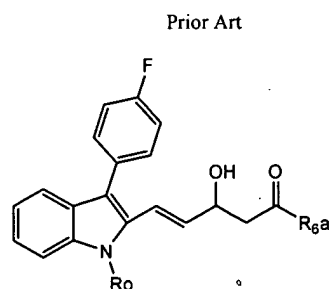
The second reference, Advanced Organic Chemistry by Jerry March, teaches the reduction ketones to alcohols and the conversion of alcohols to carboxylic acids. Ketones are reduced with reducing agents such as LiAlH₄ to form alcohols. See March, p. 809. Alcohols can be converted to carboxylic acids and their derivatives. For example, tertiary alcohols can be converted to carboxylic acid using reagents such as H₂SO₄ and CO. See. March, p. 432.

Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of Kathawala and the instant invention of Claims 19-21 is that the instant invention has a carboxylic acid or ester substituent at the 2 position, adjacent to the ring nitrogen and the prior art is the identical compound with the exception that the substituent is a ketone. See below.



Wherein R1 is C1-C6alkyl and R2 is hydrogen or a hydrocarbon radical



Wherein R6a is methyl and Ro is C1-6alkyl

(3) Finding of Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

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Kathawala is comparable to the instant invention because both compounds have the same utility as intermediates compounds of Formula (I) above; and both compounds are similar in structure with the exception that the Kathawala compound is a ketone and the instant compound is an acid or ester. However, in consideration of the teachings of March regarding standard organic reactions and reductions of ketones to alcohols and conversion of alcohols to carboxylic acids, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the ester or carboxylic acid derivative.

The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). The teaching of Kathawala together with the March would have motivated one skilled in the art to make the ester or acid of the indole derivative with the expectation that they would both be used in the synthesis of Formula (I).

CONCLUSION

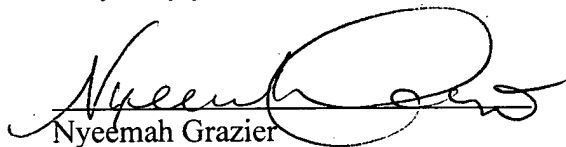
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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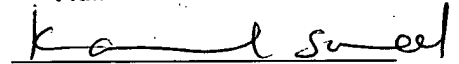
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,


Nyeemah Grazier

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